UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

PAUL HILLS,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 1:08-cv-3329
	)	
BAXTER HEALTHCARE CORP., BAXTER INTERNATIONAL, INC. and WYETH SUBSIDIARY ILLINOIS CORPORATION F/K/A SCIENTIFIC PROTEIN LABORATORIES,	)	
	)	
Defendants.	)	

PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO REMAND

Pursuant to 28 U.S.C. § 1447, Plaintiff, PAUL HILLS, by and through his attorneys, Power Rogers & Smith, P.C., in support of Plaintiff's Motion to Remand the present cause of action, states as follows:

Removal of actions from state court to federal court is governed by 28 U.S.C. § 1441, which states "any civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or the defendants, to the district court of the United States for the district and division embracing the place where such action is pending." 28 U.S.C. § 1441(a); *Fuller v. BNSF Railway Co.*, 472 F. Supp.2d 1088, 1091 (2007). Thus, "[a] defendant may remove a case to federal court **only** if the federal district court would have original subject matter jurisdiction over the action." *Id.* The analysis for this begins with the "well pleaded complaint rule" which requires federal courts to determine whether a federal question is presented on the face of a plaintiff's properly pleaded complaint. *Vivas v. Boeing Co.*, 486 F. Supp.2d 726, 729 (2007). The party seeking removal has the burden

of establishing federal jurisdiction and any doubt regarding jurisdiction should be resolved **in favor of remand**. *Id.*, *citing XL Specialty Co. v. Village of Schaumburg*, 2006 WL 2054386, at *1 (emphasis added). Wellness *Community-National v. Wellness House*, 70 F.3d 46,49 (7th Cir. 1995) Accordingly, federal courts must be cautious in entertaining "state claims with embedded federal issues" lest they "materially affect or threaten to affect the normal currents of litigation" as between federal and state courts. *Kurtz v. Fidelity Management & Research Co.*, 2007 WL 3231423 (S.D. Ill. 2007), *citing Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 319 (2005). The Seventh Circuit has further instructed that the "[c]ourts should interpret the removal statute narrowly and presume that the plaintiff may choose his or her forum." *Higbee v. Malleris*, 470 F. Supp.2d 845, 849 (2007).

In the case at bar, Plaintiff has brought a cause of action against Defendants Baxter Healthcare Corp, Baxter International, Inc., and Wyeth Subsidiary Illinois Corporation f/k/a Scientific Protein Laboratories. It is undisputed that both the Plaintiff and Defendant Baxter are domiciled in Illinois. In his complaint, Plaintiff alleges that the defendants are liable under theories of strict liability and negligence for designing, manufacturing, and distributing contaminated Heparin which proximately caused severe injuries to Paul Hills. (Ex. A, Complaint at Law).

The Defendants' sole basis for removal is the fact that the subject of the lawsuit is a pharmaceutical product which is subject to FDA regulations. Although Plaintiff cites to the Food and Drug Administration for Heparin consumer statistics and press releases regarding the product, Plaintiff's allegations are not based on violations of the FDCA or any federal statute. Put simply, Plaintiff's arguments are that the Defendants manufactured and distributed an unreasonably dangerous product.

Defendants cite *Grable & Sons Metal Products, Inc. v. Darue Eng'g & Mfg.* as support for their removal arguments. *Grable & Sons Metal Products, Inc. v. Darue Eng'g & Mfg* 545 U.S. 308 (2005). The plaintiff in *Grable* brought a quiet title action in state court against a tax sale purchaser, alleging the Internal Revenue Service (IRS) had given him inadequate notice of sale. In *Grable*, the Court found that the lawsuit presented a removable federal question. *Id.* at 308. The Court reasoned that the meaning of the federal tax provision is an important federal-law issue that belongs in federal court. *Id.* at 309. The Court distinguished the *Merrill Dow* case from the *Grable* case stating that the principal difference was the bearing of the consequences to the federal system. *Id.* The Court explained that if the federal labeling standard without a cause of action could get a state action removed to federal court, so could any other federal standards without causes of action. This would mean an enormous number of cases. *Id.* The Court granted removal in the *Grable* case because state quiet title actions rarely involve contested federal law issues. *Id.* Therefore, the *Grable* case is wholly distinguishable from the case at bar based on the Court's own application. State claims involving violations of the FDCA do not warrant federal jurisdiction and, thus, should not be removed to federal court. *Id.* 308-09.

Defendants further argue that a review of Defendants compliance with the FDCA standards will be necessary to respond to any future allegations that Defendants failed to meet these requirements. (Defendants' Notice of Removal to Federal Court, ¶6). The well-pleaded complaint rule, however, prohibits removal to federal court where federal law merely furnishes a defense to a plaintiff's claims. This matter should not be allowed to remain in federal court because of the possibility that the defendants may use a federal law to show compliance with applicable regulation.

The United States Supreme Court directly addressed the question of whether removal is appropriate for cases involving possible FDCA violations. *Merrill Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 804 (1986). In that case, the subject of the lawsuit was a drug manufacturer's negligence and alleged violation of the FDCA. In other words, plaintiff's complaint pled the violation of a federal statute as an element of a state law cause of action. *Id.* at 813. The Supreme Court upheld the lower court's interpretation that there is no federal cause of action for allegations of FDCA violations. Based upon this interpretation, the Court held that a complaint alleging a violation of a federal statute as an element of a state cause of action, when Congress has determined that there should be no private, federal cause of action for the violation, does not state a claim "arising under the Constitution, laws, or treaties of the United States" that would allow removal to federal court. 28 U.S.C. § 1331. Here Plaintiff's claims are not even based upon FDCA violations.

This Court applied and cited the *Merrill Dow* case in support of its decision to remand in *Higbee v. Malleris*. *Higbee*, 470 F. Supp.2d 845, 850 (N.D. Ill. 2007). The plaintiff in *Higbee* brought suit against his attorneys under Title VII of the Age Discrimination in Employment Act. This Court held that when the analysis of a case does not fundamentally turn on jurisprudential debates about a federal statute or act, but rather turns on the answering the more prosaic question of whether negligence occurred, removal is inappropriate. *Id.*

This Court also applied the *Merrill Dow* decision in the case of *Rubel v. Pfizer, Inc.*. *Rubel v. Pfizer, Inc.*, 276 F. Supp.2d 904 (N.D.Ill. 2003). In this case, plaintiff's complaint alleged that a drug manufacturer had been marketing drugs for "off-label" uses under the Illinois Consumer Fraud and Deceptive Practices Act. *Id.* This Court held that plaintiff had brought state law claims related to the violation of a federal statute, which does not give rise to federal

question jurisdiction. See also Seryce v. Ravenswood Hospital Medical Center, 140 F.Supp. 2nd 944 (N.D. Ill, 2001) (District remanded wrongful death action even where plaintiff alleged defendant hospital violated EMTALA.

The issue presented here is whether the defendants should be held liable under strict liability theory and whether negligence occurred in the designing, manufacturing, and distributing of an unreasonably dangerous product which Baxter has already admitted is contaminated. Although a federal law may be applicable in the proceedings, there is simply no actual dispute about federal law that would allow for removal to federal court. Following the United States Supreme Court decision in *Merrill Dow*, FDCA violations are not federal causes of action and the burden rests on the defendants to show that a substantial federal question exists that would allow for removal. The only argument proposed by Defendants is that Plaintiff may allege that the Defendants' conduct violated the FDCA in support of Plaintiff's strict liability and negligence claims. Purportedly, the defendants would then need to address these allegations by utilizing the FDCA. As stated above, the well pleaded complaint rule specifically prohibits removing a case to federal court where federal law merely furnishes a defense to Plaintiff's claims. Plaintiff's claims are asserted under state law, not federal law. Plaintiff has chosen her forum to be state court. Since any doubt with regard to jurisdiction should be resolved in favor of remand, Plaintiff requests that this Court remand the present case to the Circuit Court of Cook County, State of Illinois.

WHEREFORE, Plaintiff, PAUL HILLS, by and through his attorneys, POWER ROGERS & SMITH, P.C., respectfully requests this Honorable Court to remand the present cause of action pursuant to 28 U.S.C. § 1447.

Respectfully Submitted

POWER ROGERS & SMITH, P.C.

By: _____/s_____
Attorney for Plaintiff

Joseph A. Power, Jr.
Devon C. Bruce
POWER ROGERS & SMITH, P.C.
70 West Madison Street, 55th Floor
Chicago, Illinois 60602
Telephone: (312) 236-9381
Fax: (312) 236-0920
No. 31444

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

PAUL HILLS, Plaintiff, v. BAXTER HEALTHCARE CORP., BAXTER INTERNATIONAL, INC. and WYETH SUBSIDIARY ILLINOIS CORPORATION F/K/A/ SCIENTIFIC PROTEIN LABORATORIES, Defendants.	)	Case No. 08 L 4473

COMPLAINT AT LAW

Now comes Paul Hills, by and through his counsel, POWER, ROGERS & SMITH, and hereby states hypothetically and in the alternative as follows:

COUNT I
Baxter Healthcare & Baxter International, Inc.
(Wrongful Death- Strict Liability)

The Parties

1. Plaintiff, Paul Hills, was at all relevant times was a resident of Evanston, Illinois, Cook County.

2. Defendant, Baxter Healthcare Corporation has its principle place of business at One Baxter Parkway in Deerfield, Illinois.

3. Defendant, Baxter International Inc. has its principle place of business at One Baxter Parkway in Deerfield, Illinois.

4. At all relevant times, the registered agent for Baxter Healthcare Corporation was CT Corporation located in Cook County, Illinois.

5. At all relevant times, the registered agent for Baxter International was CT Corporation located in Cook County, Illinois.

6. Scientific Protein Laboratories is a corporation which produces ingredients for intravenous heparin. Scientific Protein Laboratories has its principle place of business in

Waunakee, Wisconsin.

7. At all relevant times, Baxter Healthcare Corporation was in the business of designing, manufacturing and distributing intravenous Heparin for profit.

8. At all relevant times, Baxter Healthcare Corporation marketed and advertised is pharmaceutical sales within Cook County.

9. At all relevant times, Baxter Healthcare Corporation employed a number of employees that worked within Cook County, Illinois.

10. At all relevant times, Baxter Healthcare Corporation sold millions of dollars worth of pharmaceutical products including intravenous Heparin to healthcare providers in Cook County, Illinois.

Contaminated Heparin

11. Heparin is a prescription drug in a class of medications called anti-coagulants also known as blood thinners.

12. Heparin is a pork-derived product and one of the oldest drugs currently still in widespread clinical use, having been used since the early 1990s.

13. Heparin works by decreasing the clotting ability of the blood, thereby preventing the actual formation of clots or preventing the extension of existing clots within the blood.

14. It is most often administered intravenously and is used primarily to decrease the chance of clots forming in patients undergoing certain medical procedures such as cardiac surgery, in preventing the formation of clots in catheters (small plastic tubes through which medication is administered or blood drawn) such as in kidney dialysis, and for other such conditions like pulmonary emboli.

15. The Food and Drug Administration ("FDA") estimates that more than 1 million multiple-dose vials are sold each month in the United States.

16. Baxter is one of the largest producers of Heparin in the United States, and its sales of heparin constitute at least a 50% market share.

17. Baxter sells an estimated 35 million units of Heparin per year, with annual sales of approximately $30 million dollars.

18. Baxter reported total sales in the amount of $11.3 billion dollars for 2007, with over 70% of its revenues being sourced form products in market-leading positions.

19. The multiple-dose heparin vials were represented by Defendants to be safe and effective

for their intended uses, including, but not limited to, intravenous administration during hemodialysis.

20. The multiple-dose heparin vials were defective in their manufacture.

21. Defendants are designers, developers, manufacturers, wholesales, retailers, fabricators, suppliers and/or distributors of the multiple-dose heparin vials, one or more of which was administered to the Paul Hills during a hemodialysis session or sessions.

22. The multiple-dose heparin vials were manufactured, fabricated, distributed, supplied and/or placed in the stream of interstate commerce by Defendants.

23. Defendants obtained the component parts for the multiple-dose heparin vials from unidentified supply companies, including, but not limited to, Scientific Protein Laboratories, which has two plants which supply the active pharmaceutical ingredient for heparin to Defendants.

24. The active pharmaceutical ingredient in heparin is an enzyme that is extracted from pig intestines.

25. One of these plants is located in China and upon information belief, has not met the requisite requirements for importation and/or sale within the United States.

26. Such requirements include, but are not necessarily limited to, inspection and approval by the Food and Drug Administration as is required for any facility to supply drug ingredients to the United States.

27. Upon information and belief, Defendants knew or should have known of such non-compliance or lack of plant inspection and/or approval, which is required for all foreign facilities.

28. Such multiple-dose heparin vials were defective at the time they were placed in the stream of commerce.

29. Baxter knew or should have known that these multiple-dose heparin vials were defective at the time they left Baxter's control and custody.

30. Defendants also knew or should have known that the multiple-dose heparin vials were causing adverse reactions for patients, such as Paul Hills.

31. Nothwithstanding their knowledge, Baxter continued to supply and sell the multiple-dose heparin vials up to and until just recently, without providing any warnings about the risks and drugs associated with the multiple-dose heparin vials to members of the public and the medical community, including Paul Hills.

32. At all material times, Baxter intentionally concealed from the public and members of the medical community, including Paul Hills, the risks and dangers associated with the use of the multiple-dose heparin vials, and/or has misrepresented the safety, quality and performance of multiple-dose heparin vials.

33. On or about January 17, 2008, Baxter and the FDA both issued press releases regarding the voluntary recall by Baxter of nine lots of Heparin Sodium Injection multiple dose vials in 1000 units/mL concentrations of 10mL and 30mL vials, 5000 units/mL concentration of 10mL vials and 10,000 units for 4mL vials.

34. This voluntary recall was the result of an abnormal increase in the reports of adverse patient reactions associated with the use of heparin.

35. These adverse patient reactions included the following: allergic or hypersensitivity-type reactions, with symptoms of oral swelling, abdominal pains, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, increased lacrimation, loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, pharyngeal edema, restlessness, vomiting/retching, shortness of breath, stomach discomfort, sweating, tachycardia, thirst, trismus, and unresponsiveness to stimul, as well as cases of severe hypotension requiring treatment.

36. These adverse reports began as early as November 19, 2007, from more than nineteen dialysis facilities in more than twelve states.

37. An estimated 40% of the adverse reports have been categorized as serious by the FDA and there have been at least four reported deaths.

38. The bulk of the adverse reports have centered on adverse events occurring at hemodialysis centers.

39. According to the FDA, there has been a significant increase in reported adverse events associated with the use of Heparin, with an estimated 350 events reported since December 2007 in contrast to less then 100 reports in 2007.

40. Based upon the clusters of adverse reports, Baxter and the Center for Disease Control ("CDC") initially identified nine specific Heparin manufacturing lots with a suggested link to those cases.

41. The initial nine lots recalled by Baxter ware for the following Heparin products: NDC#00641-2440-45, NDC#00641-2440-41, NDC#00641-2450-45, and NDC#00641-2450-41. The products include the following lots:

a. Heparin 1000 units/mL, 10mL vial, expiration date 10/2009, Lot #107054
b. Heparin 1000 units/mL, 10 mL vial, expiration date 11/2009, Lot #117085
c. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2008, Lot #047056

d. Heparin 1000 units/mL, 30 mL vial, expiration date 9/2009, Lot #097081
e. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2009, Lot #107024
f. Heparin 1000 units/mL, 30mL vial, expiration date 10/2009, Lot #107064
g. Heparin 1000 units/mL, 30mL, expiration date 10/2009, Lot #107066
h. Heparin 1000 units/mL, 30 mL, expiration date 10/2009, Lot #107074
i. Heparin 1000 units/mL, 30 mL, expiration date 10/2009, Lot #107111

42. Upon information and belief, these nine lots were all manufactured at a single facility between September and November of 207.

43. Upon information and belief, the active pharmaceutical ingredient in these products was at least in part provided by a third party supplier from an unapproved facility in China.

44. However, according to FDA updates, more recent information indicates that comparable adverse events are continuing to be reported that are associated with the use of multiple-dose heparin vials of different manufacturing lots than those identified in the initial voluntary recall.

45. The FDA began inspections of Baxter's manufacturing plant in Cherry Hill, New Jersey and its processes on or about January 16, 2008.

46. The FDA and CDC are continuing with an investigation to discover the underlying cause of these anomalous adverse events.

47. As of February 11, 2008, Baxter ceased production of all of its multiple-dose vials of injectible heparin due to the potentially life threatening adverse and allergic reactions and incidents of hypotension that are being reported.

Paul Hills

48. On or about July 24, 2007, Paul Hills had a surgical procedure performed for an abodminal aortic aneurysm at Evanston Hospital in Evanston, IL.

49. On or about July 24, 2007, the aforesaid procedure performed on Paul Hills was successful and he was expected at that point in time to have a complete and full recovery.

50. On or about July 24, 2007, Paul Hills was administered the aforesaid contaminated Heparin manufactured by Baxter.

51. Following the July 24, 2007 procedure, Paul Hills manifested signs and symptoms consistent with the administration of contaminated heparin including: dizziness, fainting, stomach pain and a fast heart rate.

52. On and after July 24, 2007, Paul Hills had an extensive hospitalization due to complications from the contaminated heparin.

53. On and prior to July 24, 2007, Baxter Healthcare manufactured and distributed the aforesaid contaminated Heparin product which was unreasonably dangerous for its intended use and was defective.

54. Prior to July 24, 2007, the aforesaid contaminated Heparin was introduced into the stream of commerce by Baxter Healthcare and/or Baxter International.

55. Prior to July 24, 2007, and at the time Baxter Healthcare and/or Baxter International introduced the aforementioned contaminated heparin into the stream of commerce the heparin contained a material defect.

56. On July 24, 2007 and at the time the contaminated heparin was administered to Paul Hills, the heparin failed to perform in the manner reasonably to be expected.

57. Prior to July 24, 2007, Baxter Healthcare and/or Baxter International failed to adequately warn of the danger of the contamination in the aforementioned contaminated heparin.

58. As a direct and proximate result of Defendants' defective multiple-dose heparin vials, Paul Hills has been injured and incurred substantial damages, including, but not limited to, medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, and other damages for which Defendants are liable.

WHEREFORE, plaintiff, PAUL HILLS, by his attorneys, POWER ROGERS & SMITH, demands judgment against Defendant, BAXTER HEALTHCARE and/or BAXTER INTERNATIONAL INC., in such sum of money in excess of FIFTY THOUSAND DOLLARS ($50,000.00) as shall represent fair and just compensation.

COUNT II
Scientific Protein Laboratories
(Wrongful Death- Strict Liability)

1. Plaintiff, Paul Hills, was at all relevant times was a resident of Evanston, Illinois, Cook County.

2. Defendant, Baxter Healthcare Corporation has its principle place of business at One Baxter Parkway in Deerfield, Illinois.

3. Defendant, Baxter International Inc. has its principle place of business at One Baxter Parkway in Deerfield, Illinois.

4. At all relevant times, the registered agent for Baxter Healthcare Corporation was CT Corporation located in Cook County, Illinois.

5. At all relevant times, the registered agent for Baxter International was CT Corporation located in Cook County, Illinois.

6. Scientific Protein Laboratories is a corporation which produces ingredients for intravenous heparin. Scientific Protein Laboratories has its principle place of business in Waunakee, Wisconsin.

7. At all relevant times, Baxter Healthcare Corporation was in the business of designing, manufacturing and distributing intravenous Heparin for profit.

8. At all relevant times, Baxter Healthcare Corporation marketed and advertised is pharmaceutical sales within Cook County.

9. At all relevant times, Baxter Healthcare Corporation employed a number of employees that worked within Cook County, Illinois.

10. At all relevant times, Baxter Healthcare Corporation sold millions of dollars worth of pharmaceutical products including intravenous Heparin to healthcare providers in Cook County, Illinois.

Contaminated Heparin

11. Heparin is a prescription drug in a class of medications called anti-coagulants also known as blood thinners.

12. Heparin is a pork-derived product and one of the oldest drugs currently still in widespread clinical use, having been used since the early 1990s.

13. Heparin works by decreasing the clotting ability of the blood, thereby preventing the

actual formation of clots or preventing the extension of existing clots within the blood.

14. It is most often administered intravenously and is used primarily to decrease the chance of clots forming in patients undergoing certain medical procedures such as cardiac surgery, in preventing the formation of clots in catheters (small plastic tubes through which medication is administered or blood drawn) such as in kidney dialysis, and for other such conditions like pulmonary emboli.

15. The Food and Drug Administration ("FDA") estimates that more than 1 million multiple-dose vials are sold each month in the United States.

16. Baxter is one of the largest producers of Heparin in the United States, and its sales of heparin constitute at least a 50% market share.

17. Baxter sells an estimated 35 million units of Heparin per year, with annual sales of approximately $30 million dollars.

18. Baxter reported total sales in the amount of $11.3 billion dollars for 2007, with over 70% of its revenues being sourced form products in market-leading positions.

19. The multiple-dose heparin vials were represented by Defendants to be safe and effective for their intended uses, including, but not limited to, intravenous administration during hemodialysis.

20. The multiple-dose heparin vials were defective in their manufacture.

21. Defendants are designers, developers, manufacturers, wholesales, retailers, fabricators, suppliers and/or distributors of the multiple-dose heparin vials, one or more of which was administered to the Paul Hills during a hemodialysis session or sessions.

22. The multiple-dose heparin vials were manufactured, fabricated, distributed, supplied and/or placed in the stream of interstate commerce by Defendants.

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24. The active pharmaceutical ingredient in heparin is an enzyme that is extracted from pig intestines.

25. One of these plants is located in China and upon information belief, has not met the requisite requirements for importation and/or sale within the United States.

26. Such requirements include, but are not necessarily limited to, inspection and approval by the Food and Drug Administration as is required for any facility to supple drug ingredients to the

United States.

27. Upon information and belief, Defendants knew or should have known of such non-compliance or lack of plant inspection and/or approval, which is required for all foreign facilities.

28. Such multiple-dose heparin vials were defective at the time they were placed in the stream of commerce.

29. Baxter knew or should have known that these multiple-dose heparin vials were defective at the time they left Baxter's control and custody.

30. Defendants also knew or should have known that the multiple-dose heparin vials were causing adverse reactions for patients, such as Paul Hills.

31. Nothwithstanding their knowledge, Baxter continued to supply and sell the multiple-dose heparin vials up to and until just recently, without providing any warnings about the risks and drugs associated with the multiple-dose heparin vials to members of the public and the medical community, including Paul Hills.

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WHEREFORE, plaintiff, PAUL HILLS, by his attorneys, POWER ROGERS & SMITH, demands judgment against Defendant, PROTEIN SCIENTIFIC LABORATORIES, in such sum of money in excess of FIFTY THOUSAND DOLLARS ($50,000.00) as shall represent fair and

just compensation.

Count III
Baxter Healthcare and Baxter International Inc.
(Wrongful Death- Negligence)

1. Plaintiff, Paul Hills, was at all relevant times was a resident of Evanston, Illinois, Cook County.

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17. Baxter sells an estimated 35 million units of Heparin per year, with annual sales of approximately $30 million dollars.

18. Baxter reported total sales in the amount of $11.3 billion dollars for 2007, with over 70% of its revenues being sourced form products in market-leading positions.

19. The multiple-dose heparin vials were represented by Defendants to be safe and effective for their intended uses, including, but not limited to, intravenous administration during hemodialysis.

20. The multiple-dose heparin vials were defective in their manufacture.

21. Defendants are designers, developers, manufacturers, wholesales, retailers, fabricators, suppliers and/or distributors of the multiple-dose heparin vials, one or more of which was administered to the Paul Hills during a hemodialysis session or sessions.

22. The multiple-dose heparin vials were manufactured, fabricated, distributed, supplied and/or placed in the stream of interstate commerce by Defendants.

23. Defendants obtained the component parts for the multiple-dose heparin vials from unidentified supply companies, including, but not limited to, Scientific Protein Laboratories, who has two plants which supply the active pharmaceutical ingredient for heparin to Defendants.

24. The active pharmaceutical ingredient in heparin is an enzyme that is extracted from pig intestines.

25. One of these plants is located in China and upon information belief, has not met the requisite requirements for importation and/or sale within the United States.

26. Such requirements include, but are not necessarily limited to, inspection and approval by the Food and Drug Administration as is required for any facility to supple drug ingredients to the

United States.

27. Upon information and belief, Defendants knew or should have known of such non-compliance or lack of plant inspection and/or approval, which is required for all foreign facilities.

28. Such multiple-dose heparin vials were defective at the time they were placed in the stream of commerce.

29. Baxter knew or should have known that these multiple-dose heparin vials were defective at the time they left Baxter's control and custody.

30. Defendants also knew or should have known that the multiple-dose heparin vials were causing adverse reactions for patients, such as Paul Hills.

31. Nothwithstanding their knowledge, Baxter continued to supply and sell the multiple-dose heparin vials up to and until just recently, without providing any warnings about the risks and drugs associated with the multiple-dose heparin vials to members of the public and the medical community, including Paul Hills.

32. At all material times, Baxter intentionally concealed from the public and members of the medical community, including Paul Hills, the risks and dangers associated with the use of the multiple-dose heparin vials, and/or has misrepresented the safety, quality and performance of multiple-dose heparin vials.

33. On or about January 17, 2008, Baxter and the FDA both issued press releases regarding the voluntary recall by Baxter of nine lots of Heparin Sodium Injection multiple dose vials in 1000 units/mL concentrations of 10mL and 30mL vials, 5000 units/mL concentration of 10mL vials and 10,000 units for 4mL vials.

34. This voluntary recall was the result of an abnormal increase in the reports of adverse patient reactions associated with the use of heparin.

35. These adverse patient reactions included the following: allergic or hypersensitivity-type reactions, with symptoms of oral swelling, abdominal pains, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, increased lacrimation, loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, pharyngeal edema, restlessness, vomiting/retching, shortness of breath, stomach discomfort, sweating, tachycardia, thirst, trismus, and unresponsiveness to stimul, as well as cases of severe hypotension requiring treatment.

36. These adverse reports began as early as November 19, 2007, from more than nineteen dialysis facilities in more than twelve states.

37. An estimated 40% of the adverse reports have been categorized as serious by the FDA

and there have been at least four reported deaths.

38. The bulk of the adverse reports have centered on adverse events occurring at hemodialysis centers.

39. According to the FDA, there has been a significant increase in reported adverse events associated with the use of Heparin, with an estimated 350 events reported since December 2007 in contrast to less then 100 reports in 2007.

40. Based upon the clusters of adverse reports, Baxter and the Center for Disease Control ("CDC") initially identified nine specific Heparin manufacturing lots with a suggested link to those cases.

41. The initial nine lots recalled by Baxter ware for the following Heparin products: NDC#00641-2440-45, NDC#00641-2440-41, NDC#00641-2450-45, and NDC#00641-2450-41. The products include the following lots:

a. Heparin 1000 units/mL, 10mL vial, expiration date 10/2009, Lot #107054
b. Heparin 1000 units/mL, 10 mL vial, expiration date 11/2009, Lot #117085
c. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2008, Lot #047056
d. Heparin 1000 units/mL, 30 mL vial, expiration date 9/2009, Lot #097081
e. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2009, Lot #107024
f. Heparin 1000 units/mL, 30mL vial, expiration date 10/2009, Lot #107064
g. Heparin 1000 units/mL, 30mL, expiration date 10/2009, Lot #107066
h. Heparin 1000 units/mL, 30 mL, expiration date 10/2009, Lot #107074
i. Heparin 1000 units/mL, 30 mL, expiration date 10/2009, Lot #107111

42. Upon information and belief, these nine lots were all manufactured at a single facility between September and November of 207.

43. Upon information and belief, the active pharmaceutical ingredient in these products was at least in part provided by a third party supplier from an unapproved facility in China.

44. However, according to FDA updates, more recent information indicates that comparable adverse events are continuing to be reported that are associated with the use of multiple-dose heparin vials of different manufacturing lots than those identified in the initial voluntary recall.

45. The FDA began inspections of Baxter's manufacturing plant in Cherry Hill, New Jersey and its processes on or about January 16, 2008.

46. The FDA and CDC are continuing with an investigation to discover the underlying cause of these anomalous adverse events.

47. As of February 11, 2008, Baxter ceased production of all of its multiple-dose vials of injectible heparin due to the potentially life threatening adverse and allergic reactions and

incidents of hypotension that are being reported.

Paul Hills

48. On or about July 24, 2007, Paul Hills had a surgical procedure performed for an abdominal aortic aneurysm at Evanston Hospital in Evanston, IL.

49. On or about July 24, 2007, the aforesaid procedure performed on Paul Hills was successful and he was expected at that point in time to have a complete and full recovery.

50. On or about July 24, 2007, Paul Hills was administered the aforesaid contaminated Heparin manufactured by Baxter.

51. Following the July 24, 2007 procedure, Paul Hills manifested signs and symptoms consistent with the administration of contaminated heparin including: dizziness, fainting, stomach pain and a fast heart rate.

52. On and after July 24, 2007, Paul Hills had an extensive hospitalization due to complications from the contaminated heparin.

53. On and prior to July 24, 2007, Baxter Healthcare manufactured and distributed the aforesaid contaminated Heparin product which was unreasonably dangerous for its intended use and was defective.

54. Baxter owed a duty to exercise reasonable care in the design, manufacture, testing, marketing, distributing, sale, and/or post-sale surveillance of these products, including the dose given to Paul Hills, so that it could be safely used for the purpose for which it was intended, or in a reasonable foreseeable manner.

55. This duty included the duty not to introduce a dangerous and unfit pharmaceutical drug, such as the multiple-dose heparin vials, into the stream of commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side effects, up to and including death.

56. In breach of their duty of care, Baxter was negligent in the manufacturer, testing, distribution, marketing, sale, and/or post-sale surveillance of the multiple-dose heparin vials, including as follows:

a. Baxter failed to exercise reasonable care in the manufacture of their multiple-dose heparin vials;

b. Baxter failed to exercise reasonable care in the inspection of their multiple-dose heparin vials;

c. Baxter failed to exercise reasonable care in the packaging of their multiple-dose heparin vials;

d. Baxter failed to provide any and adequate warnings about the risks and dangers associated with the use of their multiple-dose heparin vials, as alleged herein;

e. Baxter failed to completely, accurately and in a timely fashion, disclose the adverse events reports associated with the use of its multiple-dose heparin vials;

f. Baxter failed to recall, withdraw, and remove their multiple-dose heparin vials from the market once they knew or should have known of the risks and dangers associated with the use thereof;

g. Baxter failed to promptly respond to data, reports, and publications describing problems associated with their multiple-dose heparin vials by conducting adequate analysis, testing, and surveillance;

h. Baxter failed to implement pre-marketing and post-marketing measures to notify and warn Paul Hills , as well as his physicians, medical providers, and other members of the medical community, of the risks and dangers associated with the use of the said multiple-dose heparin vials, and to recall the defective multiple-dose heparin vials;

i. Baxter failed to adequately and reasonably establish, maintain and comport with acceptable quality control mechanisms to prevent defective products from entering the marketplace or from using unsafe ingredients;

j. Baxter failed to adequately and reasonably ensure quality controls were in the place and as such controls were adhered to obtaining the component parts for the multiple-dose heparin vials, including, but not limited to, the active pharmaceutical ingredient;

k. Baxter failed to adequately and reasonably ensure compliance with all applicable laws, regulations, and administrative approval or licensing requirements;

l. Baxter failed to adequately monitor and/or take reasonable precautions to ensure that the active pharmaceutical ingredients in heparin were of suitable quality and safety; and

m. Baxter was otherwise negligent and careless.

57. Baxter knew or should have known that patients/consumers such as Paul Hills Sean Valenzo would foreseeably suffer injury as a result of their failure to exercise ordinary care as described above.

58. Baxter's multiple-dose heparin vials were expected to and did reach Paul Hills without substantial change in the condition as designed, manufactured, marketed, distributed, and sold, prior to their administration to Paul Hills , who used the heparin as intended, or in a reasonably foreseeable manner.

59. Baxter's negligent conduct caused substantial harm to Paul Hills .

60. As a direct and proximate result of Defendants' defective multiple-dose heparin vials, Paul Hills has been injured and incurred substantial damages, including, but not limited to medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, and other damages for which Defendants are liable.

WHEREFORE, plaintiff, PAUL HILLS, by his attorneys, POWER ROGERS & SMITH, demands judgment against Defendant, BAXTER HEALTHCARE and/or BAXTER INTERNATIONAL INC., in such sum of money in excess of FIFTY THOUSAND DOLLARS ($50,000.00) as shall represent fair and just compensation.

Count IV
Scientific Protein Laboratories
(Wrongful Death-Negligence)

1. Plaintiff, Paul Hills, was at all relevant times was a resident of Evanston, Illinois, Cook County.

2. Defendant, Baxter Healthcare Corporation has its principle place of business at One Baxter Parkway in Deerfield, Illinois.

3. Defendant, Baxter International Inc. has its principle place of business at One Baxter Parkway in Deerfield, Illinois.

4. At all relevant times, the registered agent for Baxter Healthcare Corporation was CT Corporation located in Cook County, Illinois.

5. At all relevant times, the registered agent for Baxter International was CT Corporation located in Cook County, Illinois.

6. Scientific Protein Laboratories is a corporation which produces ingredients for intravenous heparin. Scientific Protein Laboratories has its principle place of business in Waunakee, Wisconsin.

7. At all relevant times, Baxter Healthcare Corporation was in the business of designing, manufacturing and distributing intravenous Heparin for profit.

8. At all relevant times, Baxter Healthcare Corporation marketed and advertised is pharmaceutical sales within Cook County.

9. At all relevant times, Baxter Healthcare Corporation employed a number of employees that worked within Cook County, Illinois.

10. At all relevant times, Baxter Healthcare Corporation sold millions of dollars worth of pharmaceutical products including intravenous Heparin to healthcare providers in Cook County, Illinois.

Contaminated Heparin

11. Heparin is a prescription drug in a class of medications called anti-coagulants also known as blood thinners.

12. Heparin is a pork-derived product and one of the oldest drugs currently still in widespread clinical use, having been used since the early 1990s.

13. Heparin works by decreasing the clotting ability of the blood, thereby preventing the

actual formation of clots or preventing the extension of existing clots within the blood.

14. It is most often administered intravenously and is used primarily to decrease the chance of clots forming in patients undergoing certain medical procedures such as cardiac surgery, in preventing the formation of clots in catheters (small plastic tubes through which medication is administered or blood drawn) such as in kidney dialysis, and for other such conditions like pulmonary emboli.

15. The Food and Drug Administration ("FDA") estimates that more than 1 million multiple-dose vials are sold each month in the United States.

16. Baxter is one of the largest producers of Heparin in the United States, and its sales of heparin constitute at least a 50% market share.

17. Baxter sells an estimated 35 million units of Heparin per year, with annual sales of approximately $30 million dollars.

18. Baxter reported total sales in the amount of $11.3 billion dollars for 2007, with over 70% of its revenues being sourced form products in market-leading positions.

19. The multiple-dose heparin vials were represented by Defendants to be safe and effective for their intended uses, including, but not limited to, intravenous administration during hemodialysis.

20. The multiple-dose heparin vials were defective in their manufacture.

21. Defendants are designers, developers, manufacturers, wholesales, retailers, fabricators, suppliers and/or distributors of the multiple-dose heparin vials, one or more of which was administered to the Paul Hills during a hemodialysis session or sessions.

22. The multiple-dose heparin vials were manufactured, fabricated, distributed, supplied and/or placed in the stream of interstate commerce by Defendants.

23. Defendants obtained the component parts for the multiple-dose heparin vials from unidentified supply companies, including, but not limited to, Protein Scientific Laboratories, who has two plants which supply the active pharmaceutical ingredient for heparin to Defendants.

24. The active pharmaceutical ingredient in heparin is an enzyme that is extracted from pig intestines.

25. One of these plants is located in China and upon information belief, has not met the requisite requirements for importation and/or sale within the United States.

26. Such requirements include, but are not necessarily limited to, inspection and approval by the Food and Drug Administration as is required for any facility to supple drug ingredients to the

United States.

27. Upon information and belief, Defendants knew or should have known of such non-compliance or lack of plant inspection and/or approval, which is required for all foreign facilities.

28. Such multiple-dose heparin vials were defective at the time they were placed in the stream of commerce.

29. Baxter knew or should have known that these multiple-dose heparin vials were defective at the time they left Baxter's control and custody.

30. Defendants also knew or should have known that the multiple-dose heparin vials were causing adverse reactions for patients, such as Paul Hills.

31. Nothwithstanding their knowledge, Baxter continued to supply and sell the multiple-dose heparin vials up to and until just recently, without providing any warnings about the risks and drugs associated with the multiple-dose heparin vials to members of the public and the medical community, including Paul Hills.

32. At all material times, Baxter intentionally concealed from the public and members of the medical community, including Paul Hills, the risks and dangers associated with the use of the multiple-dose heparin vials, and/or has misrepresented the safety, quality and performance of multiple-dose heparin vials.

33. On or about January 17, 2008, Baxter and the FDA both issued press releases regarding the voluntary recall by Baxter of nine lots of Heparin Sodium Injection multiple dose vials in 1000 units/mL concentrations of 10mL and 30mL vials, 5000 units/mL concentration of 10mL vials and 10,000 units for 4mL vials.

34. This voluntary recall was the result of an abnormal increase in the reports of adverse patient reactions associated with the use of heparin.

35. These adverse patient reactions included the following: allergic or hypersensitivity-type reactions, with symptoms of oral swelling, abdominal pains, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, increased lacrimation, loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, pharyngeal edema, restlessness, vomiting/retching, shortness of breath, stomach discomfort, sweating, tachycardia, thirst, trismus, and unresponsiveness to stimul, as well as cases of severe hypotension requiring treatment.

36. These adverse reports began as early as November 19, 2007, from more than nineteen dialysis facilities in more than twelve states.

37. An estimated 40% of the adverse reports have been categorized as serious by the FDA

and there have been at least four reported deaths.

38. The bulk of the adverse reports have centered on adverse events occurring at hemodialysis centers.

39. According to the FDA, there has been a significant increase in reported adverse events associated with the use of Heparin, with an estimated 350 events reported since December 2007 in contrast to less then 100 reports in 2007.

40. Based upon the clusters of adverse reports, Baxter and the Center for Disease Control ("CDC") initially identified nine specific Heparin manufacturing lots with a suggested link to those cases.

41. The initial nine lots recalled by Baxter ware for the following Heparin products: NDC#00641-2440-45, NDC#00641-2440-41, NDC#00641-2450-45, and NDC#00641-2450-41. The products include the following lots:

a. Heparin 1000 units/mL, 10mL vial, expiration date 10/2009, Lot #107054
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f. Heparin 1000 units/mL, 30mL vial, expiration date 10/2009, Lot #107064
g. Heparin 1000 units/mL, 30mL, expiration date 10/2009, Lot #107066
h. Heparin 1000 units/mL, 30 mL, expiration date 10/2009, Lot #107074
i. Heparin 1000 units/mL, 30 mL, expiration date 10/2009, Lot #107111

42. Upon information and belief, these nine lots were all manufactured at a single facility between September and November of 207.

43. Upon information and belief, the active pharmaceutical ingredient in these products was at least in part provided by a third party supplier from an unapproved facility in China.

44. However, according to FDA updates, more recent information indicates that comparable adverse events are continuing to be reported that are associated with the use of multiple-dose heparin vials of different manufacturing lots than those identified in the initial voluntary recall.

45. The FDA began inspections of Baxter's manufacturing plant in Cherry Hill, New Jersey and its processes on or about January 16, 2008.

46. The FDA and CDC are continuing with an investigation to discover the underlying cause of these anomalous adverse events.

47. As of February 11, 2008, Baxter ceased production of all of its multiple-dose vials of injectible heparin due to the potentially life threatening adverse and allergic reactions and

incidents of hypotension that are being reported.

48. As a direct and proximate result of Defendants' defective multiple-dose heparin vials, Plaintiff has been injured and incurred substantial damages, including, but not limited to medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, and other damages for which Defendants are liable.

Paul Hills

48. On or about July 24, 2007, Paul Hills had a surgical procedure performed for an abdominal aortic aneurysm at Evanston Hospital in Evanston, IL.

49. On or about July 24, 2007, the aforesaid procedure performed on Paul Hills was successful and he was expected at that point in time to have a complete and full recovery.

50. On or about July 24, 2007, Paul Hills was administered the aforesaid contaminated Heparin manufactured by Baxter.

51. Following the July 24, 2007 procedure, Paul Hills manifested signs and symptoms consistent with the administration of contaminated heparin including: dizziness, fainting, stomach pain and a fast heart rate.

52. On and after July 24, 2007, Paul Hills had an extensive hospitalization due to complications from the contaminated heparin.

53. On and prior to July 24, 2007, Baxter Healthcare manufactured and distributed the aforesaid contaminated Heparin product which was unreasonably dangerous for its intended use and was defective.

54. Scientific Protein Laboratories owed a duty to exercise reasonable care in the design, manufacture, testing, marketing, distributing, sale, and/or post-sale surveillance of these products, including the dose given to Paul Hills, so that it could be safely used for the purpose for which it was intended, or in a reasonable foreseeable manner.

55. This duty included the duty not to introduce a dangerous and unfit pharmaceutical drug, such as the multiple-dose heparin vials, into the stream of commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side effects, up to and including death.

56. In breach of their duty of care, Scientific Protein Laboratories was negligent in the manufacturer, testing, distribution, marketing, sale, and/or post-sale surveillance of the multiple-dose heparin vials, including as follows:

a. Baxter failed to exercise reasonable care in the manufacture of their multiple-dose heparin vials;

b. Baxter failed to exercise reasonable care in the inspection of their multiple-dose heparin vials;

c. Baxter failed to exercise reasonable care in the packaging of their multiple-dose heparin vials;

d. Baxter failed to provide any and adequate warnings about the risks and dangers associated with the use of their multiple-dose heparin vials, as alleged herein;

e. Baxter failed to completely, accurately and in a timely fashion, disclose the adverse events reports associated with the use of its multiple-dose heparin vials;

f. Baxter failed to recall, withdraw, and remove their multiple-dose heparin vials from the market once they knew or should have known of the risks and dangers associated with the use thereof;

g. Baxter failed to promptly respond to data, reports, and publications describing problems associated with their multiple-dose heparin vials by conducting adequate analysis, testing, and surveillance;

h. Baxter failed to implement pre-marketing and post-marketing measures to notify and warn Paul Hills , as well as his physicians, medical providers, and other members of the medical community, of the risks and dangers associated with the use of the said multiple-dose heparin vials, and to recall the defective multiple-dose heparin vials;

i. Baxter failed to adequately and reasonably establish, maintain and comport with acceptable quality control mechanisms to prevent defective products from entering the marketplace or from using unsafe ingredients;

j. Baxter failed to adequately and reasonably ensure quality controls were in the place and as such controls were adhered to obtaining the component parts for the multiple-dose heparin vials, including, but not limited to, the active pharmaceutical ingredient;

k. Baxter failed to adequately and reasonably ensure compliance with all applicable laws, regulations, and administrative approval or licensing requirements;

l. Baxter failed to adequately monitor and/or take reasonable precautions to ensure that the active pharmaceutical ingredients in heparin were of suitable quality and safety; and

m. Baxter was otherwise negligent and careless.

57. Baxter knew or should have known that patients/consumers such as Paul Hills would foreseeably suffer injury as a result of their failure to exercise ordinary care as described above.

58. Baxter's multiple-dose heparin vials were expected to and did reach Paul Hills without

substantial change in the condition as designed, manufactured, marketed, distributed, and sold, prior to their administration to Paul Hills, who used the heparin as intended, or in a reasonably foreseeable manner.

59. Baxter's negligent conduct caused substantial harm to Paul Hills.

60. As a direct and proximate result of this defective product, Plaintiff has been injured and incurred substantial damages, including, but not limited to medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, and other damages for which Defendants are liable.

WHEREFORE, plaintiff, PAUL HILLS by his attorneys, POWER ROGERS & SMITH, demands judgment against Defendant, SCIENTIFIC PROTEIN LABORATORIES, in such sum of money in excess of FIFTY THOUSAND DOLLARS ($50,000.00) as shall represent fair and just compensation.

Respectfully Submitted,

PAUL HILLS,

_____
Counsel for Plaintiff

Devon C. Bruce
POWER, ROGERS & SMITH
70 W. Madison Street, Suite 5500
Chicago, IL 60602
#312/236-9381
f#312/236-0920